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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. Z 190.0001-010 08/963,096 11/03/97 ZHAO **EXAMINER** HM12/0624 BENZION, G MARIANNE H. MICHEL PIONEER HI-BRED INTERNATIONAL, INC. **ART UNIT** PAPER NUMBER 7100 N.W. 62ND AVENUE 1649 P.O. BOX 1000 JOHNSTONLIS IA 50131 DATE MAILED: 06/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Application No.

08/963,096

Applicant(s)

Examiner

Office Action Summary

Gary Benzion, Ph.D.

Group Art Unit 1649

Zuo-Yu Zhao et al.



■ Responsive to communication(s) filed on 29 Mar 1999	·
★ This action is FINAL.	
☐ Since this application is in condition for allowance except for for in accordance with the practice under <i>Ex parte Quayle</i> , 1935 (· · · · · · · · · · · · · · · · · · ·
A shortened statutory period for response to this action is set to e is longer, from the mailing date of this communication. Failure to application to become abandoned. (35 U.S.C. § 133). Extension 37 CFR 1.136(a).	respond within the period for response will cause the
Disposition of Claims	
	is/are pending in the application.
Of the above, claim(s)	is/are withdrawn from consideration.
	is/are rejected.
Claim(s)	·
☐ Claims	
Application Papers	
☐ See the attached Notice of Draftsperson's Patent Drawing F	Review, PTO-948.
☐ The drawing(s) filed on is/are objected	I to by the Examiner.
☐ The proposed drawing correction, filed on	is approved disapproved.
☐ The specification is objected to by the Examiner.	
$\hfill\Box$ The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119	
Acknowledgement is made of a claim for foreign priority un	der 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the	he priority documents have been
☐ received.	
☐ received in Application No. (Series Code/Serial Numb	er)
\square received in this national stage application from the $\ln n$	ternational Bureau (PCT Rule 17.2(a)).
*Certified copies not received:	•
☐ Acknowledgement is made of a claim for domestic priority to	under 35 U.S.C. § 119(e).
Attachment(s)	
Notice of References Cited, PTO-892 ■	
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s)8
☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948	
☐ Notice of Informal Patent Application, PTO-948	
- Notice of informal Fatorit Application, 1 10-102	
SEE OFFICE ACTION ON THE	FOULOWING PAGES

Status of the Application

Claims 62-73 have been canceled and claims 74-89 newly added. Claims 74-89 are the only claims pending.

Detailed Action

Claims 72-86 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation of "A maize plant characterized in ..." fails to clearly set the metes and bounds of the claimed invention in that the limitation "characterized" is indefinite or at best superfluous. A characterization is a combination of qualities or features that distinguish one plant from another yet the limitation as set forth in the claims recites a plants affects by method steps, i.e., transformed by Agrobacterium, which in and of itself confers no qualities or features per se. Amending the claims to recite significant limitation or deletion is suggested.

Claims 79-81 rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "elite" is operationally defined and as such is indefinite. A maize plant is elite if it is adapted to the environment and meets selected ill-defined criteria. A low yielding plants which exhibits high stability under poor fertilization may be elite in one environment and exotic in another.

Claims 82-83 rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "more difficult" is indefinite in that it carries no statistically significant meaning as it is based on individual judgement and experience of the artisan. The person of skill in the art would be unable to determine where the metes and bounds of this limitation began and ended.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim74-76 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hiei et al.

Hiei et al. (US Patent # 5,591,616) disclose a maize plant that is both recalcitrant to transformation by *Agrobacterium* and that has been stably transformed with *Agrobacterium* to express a DNA of interest. As such the prior art clearly anticipated the invention as claimed.

Claims 79-81 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hiei et al.

Hiei et al. (US Patent # 5,591,616) disclose elite maize plants (B73Ht and P3732) that were stably transformation by *Agrobacterium*. As such the prior art clearly anticipated the invention as claimed.

Claim 74-86 and 88-89 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lundquist et al. (US Patent # 5,484,956).

Lundquist et al. disclose and claim transgenic maize comprising the use of elite inbred lines (OH43). Claim 1 is representative of the invention.

1. A fertile transgenic Zea mays plant of the R0 generation containing heterologous DNA encoding Bacillus thuringiensis endotoxin, wherein said DNA is expressed so that the plant exhibits resistance to an insect, wherein said expression is not present in said plant not containing said DNA, and wherein said DNA is transmitted through a complete normal sexual cycle of the R0 plant to the R1 generation, and wherein said DNA is introduced into said plant by microprojectile bombardment of Zea mays callus cells.

Accordingly, Lundquist et al. disclose the transformation of a an elite maize line that is normally recalcitrant to *Agrobacterium*, by a gene of interest, in a plant that is not A188 or B73 or hybrid therefrom, and further the production of seed and plants from the seminal transformant that comprise the DNA of interest. The method of Lundquist et al. is not that of *Agrobacterium*—mediated transformation, however, the claimed invention is set forth in product-by-process limitations and it is well taken that a product made by another process is the product disclosed—in the absence of evidence that the process introduces patentable limitations to the product. Accordingly identity of the claimed invention with that in the prior art is established. It is applicants burden to prove that the prior art composition does not anticipate or at least make obvious the invention as claimed. See, *In re Best*, 562 F.2d 1252, 195 USPQ 430 *In re Brown*,

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459 F.2d 531, 173 USPQ 685 (CCPA 1972) and *In re Marosi* 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983).

Summary

Claim 87 is considered free of the prior art and is in condition for allowance. Claims 74-86 and 88-89 are rejected as set forth above.

Inquires

Applicants amendment necessitated the new ground(s) of rejection presented in the Office Action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this or earlier communication from the examiner should be directed to Gary Benzion, Ph.D. whose telephone number is (703) 308-1119. The examiner can normally be reached on Monday-Friday from 7:00 AM to 3:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith can be reached on (703)-308-3909. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

06/21/99

GARY BENZION, PhA PRIMARY EXAMINER GROUP ART UNIT 1649